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RemarksPriority

In the Office Action of September 22, 2004 the Examiner noted that,

[S]ince no specific reference to any of the earlier filed applications (other than the two provisional applications) appears in the specification, and since there is no application data sheet describing the continuing data, the effective filing date for the purposes of this office action, is considered to be Feb. 24, 2004.

Applicants respectfully assert that the priorities claimed for the present application, although not appearing in the specification in the form of an amendment thereto, were clear as of the filing date of the present application. In support, Applicants point to the "Utility Patent Application Transmittal" sheet that accompanied the present application wherein Applicants noted in Box 17 that the present application was a continuing application of Serial No. 09/931,159 and further noted in Boxes 4b and 5 that the,

Entire disclosure of [application 09/931,159], from which a copy of the oath or declaration is supplied under Box 4b, is considered as being part of the disclosure of the [present application] and is hereby incorporated by reference therein.

Applicants respectfully note that the priorities of application 09/931,159 were clearly established during the pendency of said application and are in accord with the amendment to the specification provided herewith. Therefore, Applicants respectfully submit that there has been no waiver of priority and that no further fees or petitions are necessary in order to enter the amendment to the specification provided herewith.

Awkwardness Objection

Claim 14 stands objected to as awkward due to the presence of the following language in the claim, "diagnosed to be in need of treatment to block the estrogenic activation of estrogen dependent cancers". Applicants, by cancellation of claim 14 and through the submission of new claim 145, have replaced this language with "diagnosed as

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being in need of [a reduction in the likelihood of incurring or developing estrogen-dependent breast cancer]." Applicants respectfully assert that the presently proposed claim language is clear, not awkward and fully supported by the specification. Applicants respectfully submit that this objection has been obviated.

#### Enablement

Claims 14, 18-19, 23 and 25 stand rejected under the enablement prong of 35 U.S.C. §112, 1<sup>st</sup> paragraph. The Examiner contends:

The claimed method requires the "prevention" of breast cancer in post-menopausal women .... However, Applicant's specification provides no guidance to enable one of ordinary skill in the art to practice the claimed method. Instead there appears to be guidance on reducing the likelihood of breast cancer in post-menopausal women (please see page 20, etc.).

Without agreeing or disagreeing with any of the *In re Wands* analysis provided by the Examiner, Applicant has accepted the Examiner's invitation to alter the present claims (by canceling claim 14 and submitting new claim 145) to recite a method for "reducing the likelihood of incurring or developing estrogen-dependent breast cancer." Applicants respectfully assert that the present claims are enabled and this rejection is not applicable to any of the now pending claims.

#### Obviousness

Claims 14, 18-19, 23 and 25 stand rejected under §103(a) as obvious over the '811 patent. Applicants respectfully assert that the '811 patent, at most, could only qualify as potential prior art under 35 U.S.C. § 102(e). As noted above in the discussion about priority, the present application validly claims priority to an application filed October 30, 1996. More specifically, Applicants respectfully assert that the effective filing date of the present claim set is October 30, 1996. The '811 patent did not issue until October 1, 2002, well after the effective filing date for the present claims.<sup>1</sup> Therefore, if the '811 patent were to qualify as prior art to the present claims under §103, it would have to qualify by operation

<sup>1</sup> The earliest publication of a foreign equivalent to the '811 patent (WO 97/35571) occurred on October 2, 1997.

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of §102(c). However, the '811 patent does not qualify as prior art under 35 U.S.C. §102(c)/§103 for obviousness purposes.

Section 103(c) provides certain exceptions for the purposes of qualifying prior art. Pertinent to the present application, § 102(c) art does not preclude patentability under §103 where certain ownership status applies. Section 103(c) presently states:

(c) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

The current version of §103(c), including the exception for §102(e), is applicable to the present application. As confirmed in MPEP §706.02(1)(1), the §103(c) amendment applies to all applications filed after November 29, 1999:

Effective November 29, 1999, subject matter which was prior art under former 35 U.S.C. 103 via 35 U.S.C. 102(e) is now disqualified as prior art against the claimed invention if that subject matter and the claimed invention "were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person." **This change to 35 U.S.C. 103(c) applies to all utility, design and plant patent applications filed on or after November 29, 1999, including continuing applications filed under 37 CFR 1.53(b), continued prosecution application filed under 37 CFR 1.53(d), and reissues. (emphasis added).**

At the time the inventions of the pending claims were made, the inventors were under an obligation to assign the inventions to Eli Lilly and Company (Lilly). Also at the time of making the inventions claimed in this application, the inventors responsible for the subject matter disclosed and claimed in the cited '811 patent were under an obligation to assign said inventions to Lilly. The subject matter of the '811 patent was assigned to Lilly as reflected in assignment documents recorded at reel 013181, frame 0709. The subject matter of the present case was also assigned to Lilly as reflected in assignment documents recorded at reel 010383, frame 0447. Both cases remain owned by Lilly. The assignment documents related

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to priority application no. PCT/US97/19 were forwarded to the U.S.P.T.O. for recordation on March 5, 1999.

The common ownership provision of §103(c) is therefore met for the current claims and the cited '811 patent. The '811 patent, at most, could only qualify as potential prior art under 35 U.S.C. § 102(e). However, this application was filed after November 29, 1999, and the current version of §103(c) therefore applies to this reissue application. Also, the requisite common ownership has been set forth. Therefore, the '811 patent is disqualified as prior art under 35 U.S.C. §103. In view of this disqualification, and the confirmation of a right to a priority date of October 30, 1996 provided herewith, Applicants invite the Examiner to reevaluate the present claim set in view of qualifying art.

#### JCDOTDP: The '811 Patent

Claims 14, 18-19, 23 and 25 stand rejected under the JCDOTDP over claims 1, 7, 14 and 17 of the '811 patent. Applicants respectfully traverse this rejection.

The present application claims a method for reducing the likelihood of incurring or developing estrogen-dependent breast cancer in a post-menopausal woman diagnosed as being in need of such therapy which comprises administering orally to said woman a once-daily dose of a pharmaceutical composition wherein said composition comprises about 60 mg of raloxifene hydrochloride.

Claims 1 and 7 from the '811 patent, cover various forms of raloxifene in particulate form and claims 14 and 17 cover administering effective amounts of said forms to prevent breast cancer in a woman.

The Examiner said the then pending claims were obvious over the cited claims from the '811 patent because,

It would have been obvious to modify the claims to prevent breast cancer in a post-menopausal woman because one of ordinary skill in the art would reasonably expect raloxifene to be effective in preventing breast cancer in post-menopausal females. Moreover, the claims of [the '811 patent] are broader and encompass the more specific methods claimed in the instant application.

Concerning the dosages in claim 14 of the instant specification, it would have been obvious ... to determine dosage amounts effective in preventing breast cancer.

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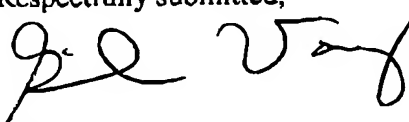
Applicants respectfully assert that the presently articulated rejection of prior claims 14, 18-19, 23 and 25 under the JCDOTDP does not establish a *prima facie* case and is not sufficient to shift the burden to Applicants to rebut said rejection whether one is looking at the presently pending claims or whether one were to do the inquiry based on the prior versions of claims 14, 18-19, 23 and 25. For example, the mere fact that a prior disclosure encompasses a new claim does not always, without further reasoning, lead to a *prima facie* case of obviousness. See, e.g., *In re Baird*, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994). Applicants respectfully submit that a re-articulation of the present rejection is necessary to shift the burden to Applicants to rebut or, in the alternative, to file a terminal disclaimer.

JCDOTDP: The '634 Patent

Claims 14, 18-19, 23 and 25 stand rejected under the JCDOTDP over claims 1-19 of the '634 patent. A terminal disclaimer may be used by Applicants to overcome this rejection.

While not necessarily agreeing with the Examiner's assessment of the claims, in order to expedite prosecution, Applicants provide a terminal disclaimer complying with 37 C.F.R. §§ 1.130(b), 1.321(c), and 3.73(b) over U.S. Patent No. 6,303,634. Pursuant to *Quad Environmental Technologies v. Union Sanitary District*, 946 F.2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991), the filing of this Terminal Disclaimer is not an admission or acquiescence by Applicants to, nor shall act as an estoppel upon the Applicants, on the merits of the rejection. Applicants maintain that said Terminal Disclaimer obviates this rejection of the pending claims.

Respectfully submitted,



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